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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 16

Serial Number: 08/026,957
Filing Date: October 29, 1993
Appellant(s): Petra Boyle et al.

James A. Giblin
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to appellant's Reply Brief on appeal filed June 5, 1995.

Claims 1-3 and 6-14 remain *provisionally* rejected under 35 U.S.C. § 101 as claiming the same subject matter as claims 1-3 and 6-14 of copending application Serial No. 08/435,246, filed May 5, 1995. Application Serial No. 08/435,246 is a File Wrapper Continuation of applicant's earlier filed application Serial No. 08/145,060, filed October 29, 1993. Applicant has not sufficiently amended the claims in the copending application to overcome this *provisional* statutory double patenting rejection. In the absence of an appropriate response by Applicant, the rejection is maintained.

The specification remains objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure for the reasons of record set forth in the Examiner's Answer. Appellants' arguments have been fully considered but are not deemed persuasive to overcome the objection. Appellant argues that they "have disclosed a biological property (specific binding) which makes the claimed product inherently useful. The demonstration of specific binding of the claimed antibody makes it immediately useful as shown in the Wabl Declaration" (see Paper No. 15, page 2, last paragraph). Further, "It is Applicant's position that a mere demonstration of binding of a new antibody to a given antigen demonstrates a biological activity which is sufficient to satisfy the requirements of 35 U.S.C. § 112 (first paragraph)" (see page 3, first paragraph). However, Appellant's arguments and the declaration of Wabl are unsupported by factual objective evidence. Indeed, the evidence of record establishes that the simple showing of specific binding of an antibody would **not** be inherently useful absent further showing of the use of that specific binding in a practical application such as therapeutics, diagnostics or purification. In the absence of a practical application of a specific binding antibody, such specific binding is little more than a laboratory phenomenon or curiosity. The Examiner does not

argue that antibodies as a class of macromolecules have not been shown to be a highly useful family. But the usefulness of a particular antibody is a function of a variety of factors such as isotype (effector function), affinity, avidity, binding properties in the presence of human serum proteins, etc. In the instant application, these factors have been addressed in the form of the prior art references of Seaver, Rhein, Natanson et al. and Hill. In attempting to overcome the deficiencies of the specification with respect to utility, Appellants have asserted that the human monoclonal anti-TNF antibodies of the instant application would be inherently useful. However, Seaver shows that antibodies are not inherently useful as diagnostic reagents. Rhein and Natanson et al. establish that anti-TNF antibodies are not inherently useful as therapeutic reagents. Hill establishes that monoclonal antibodies are not inherently useful as immunoaffinity purification reagents. Appellant argues that the claimed subject matter is not directed to diagnostics (see page 3, third paragraph), therapeutics (see page 5, second full paragraph) and that "one skilled in the art could readily accept the antibody as is or optimize the use of the antibody to attain whatever properties might be deemed appropriate, depending on the use" (see page 5, last sentence). However, all of Appellants' assertions are contrary to the facts set forth by Seaver, Rhein, Natanson et al. and Hill and Appellant has not set forth any objective evidence to overcome those facts. What remains as fact is that Appellants have failed to teach any use for their particular antibodies and, absent such teachings and guidance, one of ordinary skill in the art would not be able to use the claimed antibodies without undue experimentation. Thus, the specification fails to provide an enabling disclosure by failing to teach one skilled in the art how to **use** the claimed invention.

Appellants also challenge the Examiner's position regarding how to **make** the human monoclonal anti-TNF antibodies of the claimed invention. Appellants' arguments are directed to 1) the newly

submitted declaration of Wabl (hereafter Wabl II, attachment to Reply Brief) and 2) to the need for CMV donors (see page 6, last paragraph). Regarding the declaration of Dr. Wabl (Wabl II), Appellants submit "a second subsequently dated Declaration from Dr. Wabl in which he indicates that the patent application itself is sufficient to satisfy the enablement requirements of the patent statu[t]e" (see page 4, first paragraph). This is not persuasive. The second declaration of Dr. Wabl, like the first, represents opinion unsupported by factual objective evidence. Further, this declaration now directly conflicts with the first Wabl declaration wherein Dr. Wabl declared that one skilled in the art would need the application **and** the teachings of Appellants' work set forth in Cellular Immunology 152:569-581 (1993) (see Wabl I, page 2, paragraph #3). In the absence of objective evidence, the Wabl II declaration is of little or no probative value. With respect to the need for CMV donors, Appellants argue that the declaration of Dr. Wetzel establishes that CMV-infected donors would not be necessary and that "In any case, there are no methods of making claims or product-by-process claims in this application." Appellants' arguments are not persuasive. The declaration of Dr. Wetzel is inconsistent with Appellants' own specification for the reasons set forth in the Examiner's Answer (see paragraph bridging pages 13-14). Further, the lack of method or product-by-process claims is immaterial since 35 U.S.C. § 112, first paragraph, requires Appellants to teach how to make and use the claimed subject matter. Here, Appellants are broadly claiming human monoclonal antibodies to TNF but have not sufficiently taught one skilled in the art how to make and use such antibodies commensurate in scope with Appellants claims. In the absence of sufficient guidance or convincing objective evidence that CMV donors would or would not be required, one of ordinary skill in the art would not be able to reproduce the antibodies of the claimed invention without undue experimentation. Thus, the specification fails to teach one skilled in the art how to **make** the claimed invention.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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